UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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DURAMED PHARMACEUTICALS, INC., Plaintiff, v. WATSON LABORATORIES, INC., Defendant.	3:08-cv-0116-LRH-RAM ORDER

Before the court is plaintiff Duramed Pharmaceuticals, Inc.'s ("Duramed") motion for a temporary restraining order and preliminary injunction. Doc. #260.[1] Defendant Watson Laboratories, Inc. ("Watson") filed a response (Doc. #276) to which Duramed replied (Doc. #285).

I. Facts and Background

Plaintiff Duramed is a pharmaceutical company that researches, patents, commercializes, markets, and distributes brand name pharmaceutical drugs. On January 22, 2008, Duramed was issued U.S. Patent No. 7,320,969 ("the '969 patent") for a new extended contraceptive regimen[2] to

[1] Refers to the court's docket number.

[2] Combined oral contraceptive products have been on the market since the early 1960s. These early contraceptive regimens administered the pill on a 28-day standard cycle. For the first 21 days, a patient would take a combined active pill which included estrogen and other hormones designed to prevent pregnancy. This period was followed by a 7-day hormone-free interval in which a patient took a placebo pill in which no hormones were administered. This 28-day pill cycle would be repeated as desired to help prevent pregnancy.

An extended contraceptive regimen is the same as a traditional contraceptive regimen (a period of

be marketed under the brand name Seasonique. In contrast to traditional contraceptive regimens, Seasonique follows the active combined contraceptive cycle with seven (7) days of low-dose estrogen in place of the hormone-free placebo pill.

On March 6, 2008, Duramed filed the instant action against Watson for infringement of the '969 patent. Watson is a pharmaceutical company that develops generic versions of name brand drugs for the market. Watson filed, and was approved for, a generic drug application with the FDA to make and market a generic equivalent to Duramed's Seasonique product. In its answer, Watson challenged the validity of the '969 patent and asserted that the patent was invalid as obvious. Doc. #68.

On August 14, 2009, Duramed moved for summary judgment on Watson's affirmative defense of patent invalidity. Doc. #175. On March 31, 2010, after a hearing on the motion, the court granted Duramed's motion for summary judgment holding that the '949 patent was not obvious based upon the relevant prior art. Doc. #214. Watson appealed (Doc. #219), and on March 28, 2011, the Federal Circuit reversed this court's order granting summary judgment (Doc. #229).

After the Federal Circuit's decision, Watson indicated its intention to release its generic version of the Seasonique regimen on June 20, 2011. In response, Duramed filed the present motion for a temporary restraining order and preliminary injunction seeking to enjoin Watson from marketing and distributing its generic contraceptive. Doc. #260.

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combined hormone pills followed by a hormone-free period) except that the cycle is elongated so that the active combined pills are taken continuously for up to three months. The standard 7-day hormone free interval follows. Duramed markets a traditional extended oral contraceptive regimen under the brand name Seasonale.

II. Legal Standard

A. Preliminary Injunction[3]

A preliminary injunction is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.* (*citing Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam)). A court may only grant a preliminary injunction upon a showing that: (1) the petitioner is likely to succeed on the merits of his complaint; (2) irreparable harm will result in the absence of an injunction; (3) the balance of equities favors an injunction; and (4) an injunction is in the public's interest. *Winters v. Natural Res. Def. Council, Inc.*, 129 S. Ct. 365, 376 (2008) (citations omitted). These considerations require a plaintiff to show "serious questions going to the merits" and that "the balance of hardships tips sharply in the plaintiff's favor" before a court may issue injunctive relief. *Alliance for Wild Rockies v. Cottrell*, 622 F.3d 1045, 1050 (9th Cir. 2010).

However, in a patent infringement action, an injunction should not issue "if the party opposing the injunction raises "a substantial question concerning infringement or validity, meaning that it asserts a defense that [the party seeking the injunction] cannot prove lacks substantial merit." *Oakley Inc. v. Sunglass Hut Intern.*, 316 F.3d 1331, 1339-40 (Fed. Cir. 2003). Further, "while 'the burden of proving invalidity is with the party attacking validity,' the party seeking the injunction 'retains the burden of showing a reasonable likelihood that the attack on the patent's validity would fail.'" *Id.* (quoting *H.H. Robertson Co., v. United Steel Deck, Inc.*, 820 F.2d 384, 387 (Fed. Cir. 1987).

B. Patent Obviousness

An issued patent is presumed valid by statute. *See* 35 U.S.C. § 282. However, under the Patent Act, a patent may be deemed invalid as a matter of law "if the differences between the

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[3] The same legal standard applies to temporary restraining orders and preliminary injunctions. *See Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 839 n.7 (9th Cir. 2001) (noting that the analysis applied to temporary restraining orders and preliminary injunctions is "substantially identical").

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

A defendant proffering the affirmative defense of obviousness bears the burden to prove the patent is obvious by clear and convincing evidence. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001); *see also*, *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999). A patent invention is obvious if a person of ordinary skill in the art[4] would have had a reason to combine the particular elements or technologies in the way the claimed new invention does. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Thus, an invention is obvious when it "simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such an arrangement. *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976). Comparatively, an invention is not obvious "where vague prior art does not guide an inventor toward a particular solution." *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1347 (Fed. Cir. 2009). Further, there can be no finding of obviousness where "where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Id.* (quoting *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

Although the ultimate determination of obviousness under § 103 is a question of law, it is based on several underlying factual findings, including (1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, such as commercial success, long-felt need, and the failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

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[4] A person of ordinary skill in the art is a person presumed to think "along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985).

III. Discussion

A. *Prima Facie* Obviousness

The Federal Circuit, in its decision reversing this court's order granting summary judgment in favor of Duramed on the issue of obviousness and patent validity, specifically held that "Watson has put forth a *prima facie* case of obviousness based on the relevant prior art at the time Duramed put forth its patent application." *Duramed Pharms., Inc., v. Watson Labs, Inc.*, 2011 U.S. App. LEXIS 6309, *15 (Fed. Cir. March 25, 2011).

In its motion for injunctive relief, Duramed contends that the Federal Circuit was only viewing the issue on a narrow procedural light, and thus, the Federal Circuit's finding of a *prima facie* case of obviousness is not binding. *See* Doc. #260. However, the court finds that the Federal Circuit's holding of *prima facie* obviousness is binding upon this court. First, the court notes that the Federal Circuit had a full record before it at the time it issued its opinion, including all relevant prior art, the parties briefing on summary judgment, and the parties expert reports. Second, despite Duramed's claim of a narrow procedural posture on appeal, the Federal Circuit made specific factual findings relating to the teachings of the relevant prior art,[5] credited Duramed's low level of skill in the art,[6] and held that "[t]here appear to be no genuine issues of material fact that, based on the teachings of [the relevant prior art], one of ordinary skill would have been motivated to combine [a traditional extended oral contraceptive regimen] and 7 days of [unopposed estrogen] with a reasonable expectation that the combination would reduce the incidence of headaches associated with that regimen." *Duramed Pharms, Inc.*, 2010 U.S. App. LEXIS 6309, *21.

Additionally, the Federal Circuit specifically remanded the case to this court for the sole

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[5] *See Duramed Pharms, Inc.*, 2010 U.S. App. LEXIS 6309, *19-20 (making specific factual findings as to the teachings of the relevant prior art including Kovacs, the '749 patent, and the two Sulak articles).

[6] *See Duramed Pharms, Inc.*, 2010 U.S. App. LEXIS 6309, *19 (crediting Duramed's lower level of skill in addressing whether a reasonable person of ordinary skill in the art would have been motivated to combine the relevant prior art to reach Duramed's '949 patent.

purpose of evaluating the remaining *Graham* factor and allowing Duramed the opportunity to challenge Watson's *prima facie* cases of obviousness by introducing evidence of "secondary considerations" of nonobviousness. *Duramed Pharms., Inc.*, 2011 U.S. App. LEXIS 6309, *21 ("Duramed did not have an opportunity to challenge Watson's *prima facie* case of obviousness or introduce any secondary considerations of nonobviousness. Accordingly, we leave that determination to the district court on remand."). Therefore, the court finds that the Federal Circuit's holding that Watson has established a *prima facie* case of obviousness is binding upon this court. Thus, the only issue before the court in addressing Duramed's motion for injunctive relief is whether Duramed has proffered sufficient evidence of secondary considerations of nonobviousness to overcome Watson's *prima facie* case of obviousness and establish that Watson's patent invalidity defense lacks merit.

B. Secondary Considerations

A patent holder can negate a *prima facie* case of obviousness by proffering evidence of secondary considerations of nonobviousness. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 405 (2007). This is because "[s]econdary considerations 'may often establish that an invention appearing to have been obvious in light of the prior art was not.'" *Crocs, Inc. v. ITC*, 598 F.3d 1294, 1310 (Fed. Cir. 2010) (quoting *Stratoflex, Inc. v. Areoquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)). Thus, "[s]econdary considerations 'can be the most probative evidence of non-obviousness in the record . . . .'" *Id.* (quoting *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed Cir. 1986)). Relevant secondary considerations include: a product's commercial success; skepticism in the field; copying of the product by others; and the product meeting a long felt, but unsolved need. *See e.g., KRS*, 550 U.S. at 405 (commercial success and long felt need); *Metabolite Labs. Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1368 (Fed. Cir. 2004) (initial skepticism); *Akami Techs., Inc. v. Cable & Wireless Servs., Inc.*, 344 F.3d 1186, 1196 (Fed. Cir. 2003) (copying).

In its motion, Duramed argues that there are sufficient secondary considerations of nonobviousness to overcome Watson's *prima facie* case of obviousness and establish the validity of the '969 patent including: (1) the Food and Drug Administration's skepticism of the Seasonique regimen; (2) Seasonique's commercial success; (3) copying by other pharmaceutical companies including Watson; (4) Seasonique's "unexpected results" in reducing breakthrough bleeding during the extended cycle; and (5) the public's long felt, but unsolved need for an extended cycle oral contraceptive that reduced hormone withdrawal symptoms including headaches. *See* Doc. #260.

After reviewing the pleadings and documents in this matter, along with the attached declarations, the court finds that these secondary considerations are not sufficient to overcome Watson's *prima facie* case of obviousness. The court shall address each raised secondary consideration below.

1. Initial Skepticism

Duramed contends that there was significant skepticism about the Seasonique regimen when it was first released. In particular, Duramed argues that the Food and Drug Administration ("FDA") was so concerned about the impact of the inclusion of the unopposed estrogen during the traditional hormone-free interval that it required Duramed to undergo extensive clinical trials prior to approval despite already having an approved extended cycle oral contraceptive on the market (Seasonale). However, there is no evidence before the court that the FDA would not always require such a clinical trial of any new pharmaceutical drug which includes "novel" features like the inclusion of new chemical combinations or compounds (like the inclusion of the unopposed estrogen at issue here), the effects of which have not been clinically tested to government guidelines. Further, there is no evidence that the FDA's conduct in this case is unique to the '949 patent or that it related to any skepticism of the inclusion of unopposed estrogen rather than to the FDA's mandate to protect consumers by only allowing tested drugs which are not unduly harmful onto the market.

2. Commercial Success

Duramed argues that Seasonique is the best-selling extended regimen oral contraceptive in the United States, selling over $260,000,000 worth of the product since its launch in 2006, and therefore, the market's acceptance of the product establishes that the patent was not obvious. *See* Doc. #273, Woodford Decl., Exhibit 1, ¶¶ 24-45. However, the court finds that Duramed has not established a sufficient nexus between the sales of Seasonique and its claimed novelty (the inclusion of unopposed estrogen during the traditional hormone-free period). In order for a product's commercial success to be a valid secondary consideration of nonobviousness, the patentee must establish a nexus between the purported commercial success and the novelty of the patented product. *See Demanco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988); *see also Crocs, Inc.*, 598 F.3d at 30. Absent a sufficient nexus, a product's commercial success can be inferred on market forces unrelated to the inventiveness of the product. *Crocs, Inc.*, 598 F.3d at 31.

Here, the court finds that Duramed has failed to demonstrate how that novel aspect of the patent, the inclusion of unopposed estrogen during the traditional hormone-free period, has led to the claimed commercial success. Prior to the release of Seasonique, Duramed marketed and distributed Seasonale, a traditional extended oral contraceptive that, as Duramed claims, created the market for extended cycle contraceptives. However, upon generic introduction of similar regimens, Duramed switched its marketing and distribution focus to Seasonique. Thus, it can be inferred that sales of Seasonique are significantly linked to Seasonale's successful history rather than on the products "novelty." Further, one can infer that Seasonique's commercial success is likewise related to Duramed's heavy marketing campaign of roughly $60 to $70 million a year, rather than on the inclusion of unopposed estrogen. Therefore, based on the record before the court, the court finds that Duramed has failed to establish the required nexus between Seasonique's commercial success and the inclusion of unopposed estrogen during the traditional hormone-free period.

3. Copying of the Seasonique Regimen

Duramed argues that the fact that generic drug manufacturers[7] are pursuing the introduction of generic versions of its drug establishes the '969 patent's nonobviousness. In general, market acceptance of an invention, which can be proven through evidence of copying by others, shows that those skilled in the art considered the invention novel and innovative rather than obvious and trivial. *Akami Techs, Inc.*, 344 F.3d at 1196.

However, an initial approved generic version of a drug, like Watson's, cannot constitute evidence of copying because of the statutory incentives to copy a patented drug and challenge the patent's validity. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (providing a 180 day period of exclusivity to any first generic manufacturer of a product that successfully challenges a patent covering the drug at issue); *see also, Santarus, Inc. v. Par Pharms, Inc.*, 720 F. Supp. 2d 427, 459 (D. Del. 2009) (where evidence of copying was only an accused ANDA generic, the evidence was "not persuasive objective evidence of non-obviousness."). Further, the court finds the fact that other generic drug manufacturers desire to enter the market with a generic version of Duramed's patented drug is not, in itself, sufficient to overcome Watson's *prima facie* case of obviousness as outlined by the Federal Circuit.

4. "Unexpected Results"

In its motion, Duramed references the "unexpected results" of its Seasonique regimen in reducing breakthrough or spot bleeding during the contraceptive cycle. Duramed contends that this unexpected benefit is a sufficient secondary consideration to overcome Watson's claim of obviousness. *See P&G v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (a *prima facie* case of obviousness may be rebutted by strong evidence of unexpected results).

However, the court has reviewed the documents and pleadings relating to this secondary

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[7] Besides Watson, Duramed contends that several other drug manufacturers including Mylan Pharmaceuticals, Inc. and Lupin Pharmaceuticals, Inc. are in the process of procuring the rights to make generic versions of the drug.

consideration and finds that this evidence is not sufficient to overcome the *prima facie* case of obviousness. First, despite Duramed's claim that the Seasonique regimen reduces breakthrough bleeding, the FDA only allowed Duramed to market Seasonique as a standard contraceptive regimen. Duramed was precluded from marketing its product based on any claims that Seasonique helped reduced breakthrough bleeding. Second, there is an issue whether Duramed's claim is even properly considered by the court because Duramed tested the Seasonique regimen against an internal, nonpublic, company manufactured drug, and not against the closest prior art which was Duramed's Seasonale brand. *See e.g., Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 970 (Fed. Cir. 2006) ("[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared to the closest prior art."). Thus, there is insufficient evidence before the court that Seasonique was any better than other extended contraceptive regimens on the market, including Seasonale, at reducing breakthrough bleeding to overcome Watson's *prima facie* case of obviousness.

5. Long-felt, But Unsolved Need

Finally, Duramed argues that there was a long-felt need for its invention, but that the need had been unsolved until its patent. Specifically, Duramed claims that there was a need for an extended contraceptive regimen that reduced the traditional complaints of extended regimens like breakthrough bleeding. The general assumption is that a long felt unsolved need points to nonobviousness because if there had been such a need and its solution was so obvious, an ordinary artisan would have found that solution prior to the patent. *See KRS*, 550 U.S. at 405-06.

However, once again there is insufficient evidence before the court that Seasonique was better than other drugs on the market, including its own product Seasonale, at preventing breakthrough bleeding. This is evidenced by the fact that the FDA did not allow Duramed to market this proclaimed benefit. Thus, even if there was a long felt need for a product that reduced breakthrough bleeding during an extended cycle, the Seasonique regimen could not have satisfied

that need in the public's mind because the benefit was unknown.

Therefore, based on the record before the court, the court finds that Duramed has not proffered sufficient evidence of secondary considerations of nonobviousness to overcome Watson's *prima facie* case of obviousness. As such, the court finds that Duramed has not raised serious questions that Watson's patent invalidity defense lacks merit to warrant Duramed's requested injunctive relief. Accordingly, the court shall deny Duramed's motion for a temporary restraining order and preliminary injunction.

IT IS THEREFORE ORDERED that plaintiff's motion for a temporary restraining order and preliminary injunction (Doc. #260) is DENIED.

IT IS SO ORDERED.

DATED this 16th day of June, 2011.

LARRY R. HICKS
UNITED STATES DISTRICT JUDGE